

*Convalescent plasma in the Treatment of COVID 19*

Principal Investigator: Latha Dulipsingh, MD

NCT04343261

Donor Consent

Version 4

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## INFORMED CONSENT FOR INVESTIGATIONAL PROTOCOLS AT TRINITY HEALTH OF NEW ENGLAND

STUDY TITLE: *CONVALESCENT PLASMA IN THE TREATMENT OF COVID 19 (PLASMA DONOR)*

PRINCIPAL INVESTIGATOR: *LATHA DULIPSINGH, M.D.*

CO-INVESTIGATOR: *DANYAL IBRAHIM, M.D.*

**This is a clinical trial (a type of research study). This research study includes only patients who choose to take part. This consent form explains the research study and your part in the study. Please read it carefully and take as much time as you need. Please take your time to make your decision. Your participation is voluntary.**

**You are being asked to take part in this study because you have tested positive and recovered from *coronavirus 2(SARS-CoV-2)/COVID-19*.**

**The epidemic of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)/COVID-19 originated in Wuhan, China in Dec 2019 and has rapidly spread worldwide. On March 11<sup>th</sup> 2020, the World Health Organization (WHO) declared this a pandemic, and as of March 30<sup>th</sup> over 737,929 people in 177 countries have been affected with a total of 34,800 deaths. As of March 30<sup>th</sup> 2020, the United States has reported 143,055 positive cases and 2513 deaths.**

**Currently there are no approved treatment options for COVID-19 and there are trials underway for antiviral medications (drugs that fight viruses). There is evidence that plasma (the liquid portion of blood) from individuals who have recovered from certain viral infections contain antibodies. This plasma has been used to treat patients who are currently infected with that virus. A very recent publication showed a case series of 5 critically ill patients with COVID-19 and Acute Respiratory Distress Syndrome (ARDS) who were treated with convalescent plasma containing neutralizing antibody and detected an improvement in the patients' clinical status.**

**The purpose of this study is to collect blood from previously COVID-19 infected persons who have recovered and use it as a treatment for those who are currently sick with a severe or life-threatening COVID-19 infection.**

**Once you have decided to participate in the study, you will be asked to donate 500 cc of your plasma. You will be in the study for as long as it takes to donate your blood, approximately 2-4 hours.**

**There are risks to your participation that are described later in this consent form. Some of the risks may include:**

- **light-headedness,**



- fainting,
- blood loss,
- injection site irritation or infection,
- muscle cramping and allergic reaction.

There is not a direct benefit to you for your participation in the study however your participation may help others in the future who are diagnosed with *COVID-19*.

You may choose not to participate in this study. If you are interested in learning more about this study, please continue reading the information below.

## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to find out what effects (good and bad) plasma (the liquid portion of your blood) from patients, like you, who have recovered from a COVID-19 infection, has on people with a severe or life-threatening COVID-19 infection. This research is being done because there is no Food and Drug Administration (FDA) approved treatment for the COVID-19 infection at this time.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY

About 300 people will be contacted to take part in this study at Trinity Health Of New England sites (Saint Francis Hospital and Medical Center, Saint Mary's Hospital, Mercy Hospital, Mount Sinai Hospital and Johnson Memorial Hospital).

## WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, the following information will be collected:

- Proof of your identity and postal address
- Indicate the last date you donated blood or blood components
- Your medical history (including information about your COVID-19 infection) will be reviewed
- A physical assessment will be completed (temperature, blood pressure, hemoglobin/hematocrit level, pulse, weight, skin examination)
- You will be tested to confirm you are negative for COVID-19 by a nasal(nose) swab and in some people we will test using the nasal swab and a saliva(spit)sample. The spit sample will only be collected in some patients to see if the test compares to the nasal swab.
- Blood will be drawn to measure the level of antibodies and viral load

If your COVID-19 retest comes back positive, we would like you to come back in 10 days for another test and your blood will be drawn again.



**Once your COVID-19 test is negative you will be referred to the New York Blood Center (locations in Rhode Island and Connecticut) where plasma is obtained according to NYBC Standard Operating Procedures (SOP) for plasma collection.**

**Donating plasma is similar to giving blood. A needle is placed into a vein in your arm. Plasma is collected through a process call plasmapheresis and is conducted in cycles that may take up to an hour. Whole blood is drawn. The plasma is separated from the red blood cells and other cellular components. These are returned to your body with sterile saline solution to help the body replace the plasma removed from the whole blood. To collect the plasma (the liquid portion of your blood), an apheresis machine (a machine) will be connected to both of your arms. This machine will collect a small amount of your blood and separate the components. A small amount of the plasma is collected and the remaining part of your blood is returned to your body. This process is repeated several times over about a 2 hour period.**

## **HOW LONG WILL I BE IN THE STUDY?**

**You will be in the study for 2-4 hours, the time it normally takes to collect 500 cc (about 2 cups) of plasma. After you donate the blood, you will be given a snack and a drink.**

**The researcher may decide to take you off this study if your blood product is determined not suitable (does not contain enough of the desired components to fight COVID-19).**

**You can stop participating at any time. However, any information collected prior to your decision to stop participation may be used as part of this study. You may request to have any blood products collected as part of this study destroyed, if they have not already been used, as part of this study. If you decide to stop participating in this study, we encourage you to talk to the researcher and your regular doctor first.**

## **What Happens to the Samples Obtained During this study?**

Your name will be removed from all samples before they are sent to the research labs. Upon completion of the study, or upon your withdrawal, the sample will be kept in storage until fully utilized. The sample will forever be separated from your identity, and there will be no way, not even through codes, to link the sample back to you. These de-identified samples may be shared with other researchers and used in other projects. If you choose to withdraw from the study after your sample(s) has been obtained, data collected before your withdrawal from the study will remain in the research database. You will not be informed of your specimen results. We will store your blood/saliva(only if taken) samples for future studies.

## **WHAT ARE THE RISKS OF THE STUDY?**

**While on the study, you are at risk for the side effects listed below. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. We will follow procedures which will make these side effects less serious**



**and uncomfortable. Many side effects go away shortly after the plasma collection is finished, but in some cases, side effects can be serious or long-lasting or permanent.**

**Risks and side effects related to the plasma collection process include:**

- **Side effects from intravenous needle insertion site: skin irritation, pain, swelling, bleeding, bruising and infection.**
- **Other symptoms include light-headedness, dizziness, nausea after drinking, eating, and resting.**
- **Minimal risk of re-exposure to the virus**

**Risks to pregnant women: Women who are pregnant at the time or have been pregnant within the last 6 weeks will be excluded from participation.**

**Social risks: There is a chance that people outside of the research team may learn of your study participation.**

**For more information about risks and side effects, ask the researcher or contact the Principal Investigator, Latha Dulipsingh, MD at 860-714-4402.**

**During the research study, you will be notified of newly discovered side effects which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.**

## **WHAT SAFEGUARDS WILL BE USED?**

**Once the plasma is collected it will be de-identified and there will be a Master Code Key that will be maintained as a separate record in a password protected and encrypted computer. All private medical health records, tests and results will be kept with research staff in a locked office and locked cabinet for privacy and confidentiality protection. We also de-identify any personal identifiers from the records and all electronic data will be saved in password protected and encrypted hard drives.**

## **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

**If you agree to take part in this study, there may not be a direct medical benefit to you. We hope the information learned from this study will benefit other patients diagnosed with *COVID-19* in the future.**

**During the research study, you will be notified of newly discovered significant findings. You may also be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.**

## **WHAT OTHER OPTIONS ARE THERE?**

**You have the option not to participate in this study and not to donate plasma for this study.**



## WHAT ABOUT CONFIDENTIALITY?

### **Your confidentiality will be guarded to the greatest extent possible.**

**Trinity Health Of New England conforms to the Health Insurance Portability and Accountability Act (HIPAA). Your medical records will be maintained in accordance with state and federal laws. Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Private identifiable information about you may be used or disclosed for purposes of this research project as described in the study's authorization form.**

**You have the right to access your medical records. You may request that your medical record be released to your personal physician.**

**Please refer to the Trinity Health Of New England Notice of Privacy Practice for more information on how medical information about you may be used or disclosed.**

## WHAT ARE THE COSTS?

**Taking part in this study may lead to added costs to you or your insurance company, and any costs not covered by your insurance will be your responsibility.**

**Transportation to the Blood Center will be provided by the study. If you choose to use your own vehicle/car, we will reimburse you \$0.60 per mile.**

**Please note, the Investigator is required to provide your name and Social Security Number to the Trinity Health Of New England site Accounting Department in order for you to receive payment. Trinity Health Of New England sites are required to report payments totaling \$600 or more to the Internal Revenue Service (IRS). This means if you receive \$600 or more from a site within Trinity Health Of New England during the calendar year, your compensation will be reported to the IRS and you will receive a 1099 Form.**

**Trinity Health Of New England sites may not be financially responsible for costs associated with this study. Please ask about any expected added costs or insurance problems.**

**In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. If you sustain injuries from your participation in this research study, you may not be compensated by Trinity Health Of New England. You or your insurance company will be charged for continuing medical care and/or hospitalization.**

## WHAT ARE MY RIGHTS AS A PARTICIPANT?



**Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.**

**We will tell you about new information that may affect your health, welfare or willingness to stay in this study.**

**A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare or willingness to stay in this study.**

**If you change your mind after signing this consent, you have the right to revoke your consent, in writing, at any time.**

## **WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

**For questions, concerns or a research-related injury, please contact the Principal Investigator, Latha Dulipsingh, MD at 860-714-4402.**

**For questions about your rights as a research participant, use of protected health information, research related concerns or complaints, please contact the Trinity Health Of New England Institutional Review Board (which is a group of people who review the research to protect your rights) at 860-714-4068. You may also write to:**

**Institutional Review Board  
Trinity Health Of New England  
260 Ashley Street, 3<sup>rd</sup> floor  
Hartford, CT 06105**

**You may also contact the Institutional Review Board to obtain information or to offer input with an informed individual unaffiliated with this specific research protocol or in case you are not able to reach the research team, or wish to talk to someone not on the research team.**

## **WHERE CAN I GET MORE INFORMATION?**

**You may call the Principal Investigator, Latha Dulipsingh, MD at 860-714-4402 for additional information.**

**You will get a copy of this form.**

**If information has arisen that is clinically important to you, it is the responsibility of the Principal Investigator to share this information with you and check if it affects your willingness to participate in the research.**

## **DISCLOSURE OF BENEFITS TO INVESTIGATORS INVOLVED IN THE STUDY**

**There is no direct benefit to the investigators for participating in this study.**

## **SIGNATURES**



**By signing this form I acknowledge that I have read or have had read to me this informed consent document and have been given the opportunity to ask questions and have them answered. I voluntarily agree and consent to take part in this study as described in this document.**

\_\_\_\_\_  
Signature of Participant (Print Name) Date

\_\_\_\_\_  
Signature of Person Obtaining Consent (Print Name) Date

**\*If obtaining verbal consent from the participant there should be a witness signature along with a person obtaining consent**

Name of Subject: \_\_\_\_\_

\_\_\_\_\_  
Witness Signature for Telephone Consent (Print Name) Date

\_\_\_\_\_  
Signature of Person Obtaining Telephone Consent (Print Name) Date

Since this is a high profile study you may be asked to participate in media releases. In addition to an opt in for that you will also sign an additional disclosure form at that time.

\_\_\_\_\_(Initials) I would be interested in media opportunity

\_\_\_\_\_(Initials) No, I am not interested in any media disclosure of my participation





## Research Authorization for Use/Disclosure of Protected Health Information

Participant Name: \_\_\_\_\_

In connection with my participation in the research study described below at Trinity Health Of New England, I, the undersigned participant, understand that private identifiable health information about me will be obtained, used and disclosed for purposes of the research project. Accordingly, I hereby authorize the use or disclosure of my health information, including, if applicable, protected drug and/or alcohol abuse, confidential HIV-related and psychiatric information (“Protected Health Information”) in the manner described herein, for purposes related to my participation in the following research study (the “Research Study”): ***Convalescent plasma in the treatment of COVID 19 (Plasma Donor)***

Such purposes shall include all activities related to the conduct of the research study, as well as activities that ensure that my rights as a participant in a research study are being protected and that the research is being conducted properly.

### **I. Information Covered by Authorization.**

The Protected Health Information that may be used or disclosed in connection with this authorization includes the following: *[check all applicable items]*

- ☒ Existing medical records or information accessed by researchers as part of Research Study;
- ☒ Information from interviews and questionnaires conducted as part of Research Study, including medical history;
- ☒ All data obtained during any study procedure;
- ☒ All medical records or reports created in connection with Research Study; such as any radiology reports, lab results, psychological test results, consultation reports, results of physical examinations, summary notes and treatment records;
- ☐ Other *[describe]*:

### **II. Authorized Uses/Disclosures.**

Information about your participation in this research study may be included in your medical record, which is used throughout Trinity Health Of New England sites. Doctors outside of Trinity Health Of



New England sites may not have access to this information. This form authorizes the following persons or entities to obtain, use or disclose my Protected Health Information in connection with the Research Study:

- The Principal Investigator, Latha Dulipsingh, MD
- The Co-Investigator, Danyal Ibrahim, M.D.
- Any research or Trinity Health Of New England staff working under the principal investigator's or any co-investigator's direct supervision

The Protected Health Information may be disclosed to the following *[check applicable items]*:

- X Trinity Health Of New England Research Department staff or Institutional Review Board Members;
- X Any government agency overseeing this research at Trinity Health Of New England site for which authorization would be required by law;
- X The research sponsor, Trinity Health Of New England
- X New York Blood Center
- X My physician, , for purposes of providing information about my health to my regular physician;
- X Other researchers for data comparison purposes, provided data used for this purpose is stripped of personally identifying information;

### **III. General Provisions.**

I understand that by signing this authorization I agree to the use and disclosure of my protected Health Information as described above. I understand that I am not required to sign this authorization, but if I do not sign this authorization, I may not participate in the Research Study. My decision not to sign this authorization will not affect my ability to obtain future treatment from a Trinity Health Of New England site or any health care provider named in this authorization, except for any research-related treatment.

I understand that I am entitled to a copy of this authorization form. I agree that a copy of this authorization will be as valid as the original. I understand that I may revoke this authorization at any time by notifying Latha Dulipsingh, M.D. in writing, but if I do it won't have any effect on actions taken prior to receipt of the revocation. If I revoke this authorization, I understand that once revoked, Trinity Health Of New England sites and the investigators named above may continue to use or disclose my Protected Health Information as necessary to maintain the integrity and reliability of the Research Study. I will send any notice of my desire to revoke this authorization to:

Latha Dulipsingh, M.D.  
Diabetes and Endocrinology Center  
1075 Asylum Avenue, Hartford, CT 06105

This Authorization does not have an expiration date.

I understand that under applicable law recipients of my Protected Health Information may not be subject to the federal privacy laws. Consequently, information disclosed under this authorization may be subject to further disclosure by the recipient and may no longer be protected by the federal



privacy regulations. Such information, however, may continue to be protected for recipients that are subject to the federal privacy regulations or other state or federal confidentiality laws or contractual confidentiality obligations.

I understand that I may obtain a copy of the Trinity Health Of New England Privacy Notice for a description of the Hospital's privacy practices for protected health information, and that I have a right to review such Notice's before signing this authorization.

\_\_\_\_\_  
Participant Signature (or authorized representative)

\_\_\_\_\_  
Date

Print Name: \_\_\_\_\_